K121015

MAY - 4 2012

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

Submitter's Name	Abbott Vascular
Submitter's Address	3200 Lakeside Drive, Santa Clara, CA 95054
Telephone	(408) 845-0682
Fax	(408) 845-3743
Contact Person	Ivalee Cohen
Date of Submission	March 30, 2012
Device Trade Name	Emboshield NAV^6 Embolic Protection System
Device Common Name	Embolic Protection System
Device Classification Name	Catheter, Carotid, Temporary, for Embolization Capture
Device Classification	Class II
Product Code	NTE
Predicate Device Names	• Emboshield NAV^6 Embolic Protection System (K081523) • Emboshield NAV^6 Embolic Protection System (K090665) • Emboshield NAV^6 Embolic Protection System (K110909)
Summary of Substantial Equivalence	• The proposed Emboshield NAV^6 Embolic Protection System has the same intended use as the predicate devices. • Testing results have demonstrated that the Emboshield NAV^6 Embolic Protection System is substantially equivalent to the predicate device.

Device Description:

The Emboshield NAV^6 Embolic Protection System (EPS) is a temporary percutaneous transluminal filtration system designed to capture embolic material released during angioplasty and stent procedures within carotid arteries. The system consists of the following components:

- BareWire Filter Delivery Wire:

The BareWire Filter Delivery Wire is a 0.014" PTFE coated stainless steel guidewire with a 3 cm (0.014") platinum/nickel radiopaque distal tip section. Three (3) BareWire designs are available as separately packaged items offering different support levels. The BareWire Workhorse is supplied with the Emboshield NAV^6 Embolic Protection System and is available packaged separately in two lengths, 315 cm and 190 cm.

- RX Delivery Catheter:

The RX Delivery Catheter usable length is 135 cm. The crossing profile is between 0.0365" and 0.0415", depending on Filtration Element size. A pull handle is used to deploy the loaded Filtration Element from the pod. Two (2) pairs of indicator bands are provided along the catheter shaft; a proximal pair (90 cm and 100 cm from the catheter tip) to indicate the catheter tip position during advancement through the guide catheter, and a distal pair to indicate the proximity of the RX exit port during catheter retraction. A radiopaque marker band is positioned proximal to the pod.

- Filtration Element:

The Filtration Element consists of a nylon membrane with an internal nitinol support structure with radiopaque coils. There are two proximal triangular entry ports and multiple 120 micron distal perfusion pores. There is also a proximal and a distal marker band. The Filtration Element is available in two sizes; small (ϕ5.0 mm) to treat vessel diameters of 2.5 – 4.8 mm and large (ϕ7.2 mm) to treat vessel diameters of 4.0 to 7.0 mm.

- RX Retrieval Catheter:

The RX Retrieval Catheter has a usable length of 139 cm and a molded expansile distal tip with a maximum outer diameter of 0.067". A handle is situated at the proximal end. Two pairs of marker bands indicate the position of the Retrieval Catheter RX guidewire exit port and catheter tip.

Indication for Use:

The Emboshield NAV^6 Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus / debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.5 and 7.0 mm.

Technological Characteristics:

The modification being implemented is to change the adhesive used to attach the radiopaque marker onto the delivery catheter component of the NAV^6 system. No other changes were made to the device cleared under K110909. Therefore, the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

Performance Data:

Performance testing was successfully completed on the Emboshield NAV^6 Embolic Protection System. The following tests were conducted:

- Biocompatibility
  - Cytotoxicity
  - Hemocompatibility
    - Hemolysis, Direct and Indirect
    - Complement Activation Test
  - Coagulation (PT and PTT)
  - Acute Systemic Toxicity
  - Intracutaneous Toxicity (Irritation)
  - Sensitization
  - Material-Mediated Pyrogenicity
- Tensile Testing: Marker Band Integrity – Baseline, and 2 and 3 years Accelerated Aging

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 4 2012

Ms. Ivalee Cohen
Manager, Regulatory Affairs
Abbott Vascular Inc.
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K121015
Trade/Device Name: Emboshield Nav^6 Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: March 30, 2012
Received: April 4, 2012

Dear Ms. Cohen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. S. Hillebrenner

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121015

Device Names: Emboshield NAV^6 Embolic Protection System

Indications for Use: The Emboshield NAV^6 Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus / debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.5 and 7.0 mm.

Prescription Use__X__ (Per 21 CFR 801 Subpart D) OR Over-The-Counter_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. S. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121015